K043197

MAY 2 0 2005

510(k) Summary

Submitter	LifeScan, Inc. 1000 Gibraltar Drive Milpitas, CA 95035
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Date Summary Prepared	May 18, 2005
Classification Name	(1) OneTouch® Ultra® Test Strip and OneTouch® Ultra® Family of Blood Glucose Monitoring Systems (OneTouch® Ultra®, OneTouch® InDuo® and OneTouch® UltraSmart®) Common name: Glucose test system Classification: Blood Glucose Meters and Test Strips are Class II devices (21 CFR Section 862.1345, Glucose Test System) (2) OneTouch Ultra Control Solution is a Class I device (21 CFR Section 862.1660, Single Analyte Control.) (3) UltraSoft Blood Sampler and Sterile Lancet – Sterile Lancet, Lancing Device and accessories are Class I (exempt) devices (21 CFR Section 878.4800, Lancet, Blood.
Predicate Devices	OneTouch® Ultra® Test Strip OneTouch® Ultra® Blood Glucose Monitoring System OneTouch® InDuo® Blood Glucose Monitoring System OneTouch® UltraSmart® Blood Glucose Monitoring System

Device Description
The OneTouch Family of Systems consists of the OneTouch Ultra, InDuo or UltraSmart Meter, OneTouch Ultra Test Strips, OneTouch Ultra Control Solution, UltraSoft Lancing Device, UltraClear Cap and UltraSoft lancets. The OneTouch Ultra meter, when used with the OneTouch Ultra Blood Glucose Test Strips, quantitatively measures glucose in capillary whole blood. The OneTouch Ultra Control Solution verifies the performance of the OneTouch Ultra Blood Glucose Test Strips.

Intended Use
The OneTouch® Ultra® Family of Systems are intended to be used for quantitative measurement of glucose in fresh capillary whole blood. The OneTouch Ultra Family of Systems are intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

The OneTouch Ultra Family of Blood Glucose Monitoring System is specifically indicated for use on the finger, arm or palm.

Comparison to Predicate Device System
The modifications to the OneTouch Ultra Family of systems encompass changes to the intended use (and associated labeling changes) for the OneTouch Ultra Test Strips. The intended use has been expanded to include palm testing. The labeling has been modified to expand the Alternative Site Testing (AST) sites to include the palm of the hand. Clinical testing demonstrated that palm and finger glucose measurements are equivalent during the steady state. In addition, incremental changes to the device systems have been addressed.

Technological Characteristics
There has been no change to the fundamental scientific technology.

Summary of Performance Characteristics
There has been no change to the performance characteristics of the device systems.

Conclusion
The modified intended used and associated labeling changes for the OneTouch Ultra Test Strip and OneTouch Family of Blood Glucose Monitoring Systems are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Mary Ellen Holden
Sr. Regulatory Submissions Specialist
LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035-6312

MAY 2 0 2005

Re: k043197
Trade/Device Name: OneTouch® Ultra® Blood Glucose Monitoring System
OneTouch® InDuo® Blood Glucose Monitoring System
OneTouch® UltraSmart® Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA, NBW
Dated: April 19, 2005
Received: April 20, 2005

Dear Ms. Holden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043197

Device Name: OneTouch® Ultra® Blood Glucose Monitoring System

Indications for Use:

The OneTouch® Ultra® Blood Glucose Monitoring System is intended to be used for quantitative measurement of glucose in fresh capillary whole blood. The OneTouch® Ultra® System is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

The OneTouch® Ultra® Blood Glucose Monitoring System is specifically indicated for use on the finger, arm or palm.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X_____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Updated August 30, 2004

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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Indications for Use

510(k) Number (if known): K043197

Device Name: OneTouch® InDuo® Blood Glucose Monitoring System

Indications for Use:

The OneTouch® InDuo® System is intended to be used for quantitative measurement of glucose in fresh capillary whole blood. The OneTouch® Ultra® System is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

The OneTouch® InDuo® Blood Glucose Meter also functions as the cap for the InDuo® Insulin Doser. The two devices fit together to form a single unit for user convenience.

The OneTouch InDuo® Blood Glucose Monitoring System is specifically indicated for use on the finger, arm or palm.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X____ (21 CFR 801 Subpart C)

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510(k) K043197

Indications for Use

510(k) Number (if known): K043197

Device Name: OneTouch® UltraSmart® Blood Glucose Monitoring System

Indications for Use:

The OneTouch® UltraSmart® System is intended to be used for quantitative measurement of glucose in fresh capillary whole blood. The OneTouch® Ultra® System is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

The OneTouch UltraSmart® Blood Glucose Monitoring System provides the user with electronic logbook functions that store data such as insulin and oral medication doses, food intake, amount of exercise, and health information such as illness. The meter includes a data port that enables the user to download electronic data to a personal computer.

The OneTouch® UltraSmart® Smart Blood Glucose Monitoring System is specifically indicated for use on the finger, arm or palm.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _X___ (21 CFR 801 Subpart C)

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